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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.        | CONFIRMATION NO.       |
|--|-------------|----------------------|----------------------------|------------------------|
| 10/532,662   | 01/19/2006  | Satoshi Omura        | 8012-1317                  | 5881                   |
| 466 7590 05/16/2008<br>YOUNG & THOMPSON<br>209 Madison Street<br>Suite 500<br>ALEXANDRIA, VA 22314 |             |                      | EXAMINER<br>AUDET, MAURY A |                        |
|  |             |                      | ART UNIT<br>1654           | PAPER NUMBER           |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/532,662

**Applicant(s)**

OMURA ET AL.

**Examiner**

MAURY AUDET

**Art Unit**

1654

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 7-10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 16 is/are allowed.
- 6) ☒ Claim(s) 15 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 7-10, 13-15, and 17-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

The present application has been transferred from former Examiner Young to the present Examiner.

The amendment and response of 1/21/08 are acknowledged. Claims 1-2, 7-10, and 13-19 remain pending. Claim 2 is withdrawn from consideration. Claims 1, 7-10 and 13-19 remain examined on the merits.

Following the pre-Appeal conference, the 35 USC 103 Finality has been withdrawn. The present Examiner finds no motivation or suggestion to arrive that the 6 methylated/methylated chains coming off the core of either Kalbe I or II.

This is further corroborated by Applicant's findings of unexpected results using the specific compound of FKI-1033 v. the known core compound of Kalbe I/II, further strengthening Applicant's arguments that there was no suggestion/motivation to select out of the laundry list genus of either Kalbe I or II. Namely, as Applicant's noted on p. 17 of the last response::

In the declaration, the toxicity of FKI-1033 was compared to emodepside against adult cattle ticks. Emodepside is "particularly preferred" by KALBE '268 (e.g. paragraph 48 of the U.S. equivalent US 2003/0125244 A1, or page 12, lines 9-10 of the WO document). In emersion tests, FKI-1033 killed 100% of ticks at 20 ug/ml, but emodepside did not kill any ticks at 100 ug/ml. In injection tests, FKI-1033 killed 100% of the ticks at 0.16 ug/ml, and emodepside killed 100% of the ticks at 20 ug/ml. Thus, FKI-1033 proved to be far more potent than Emodepside in anthropepocidal activity (See Item 1 of the declaration).

KALBE '268 also fails to recognize depsipeptides that would have a ryanodine binding inhibition activity. FKI-1033 unexpectedly showed 50% ryanodine binding inhibition activity

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against the American cockroach ryanodine receptor at 4.2 uM, and all tested 24 ring cyclic depsipeptides (bassianolide and PFI022A, or PF 1022 as disclosed by KALBE) and 18-ring cyclic depsipeptides (cnniatin A and beauvericin) showed no binding inhibition at 110 uM (Item 2 of the declaration).

Thus, Finality has been dropped. However, the present action is made Non-Final based on other New Rejections of record.

#### ***Restriction made Final***

As previously stated by the former Examiner, Applicant's election with traverse of Group I, claims 1, 7-10 and 13-15 in the reply filed on October 23, 2006 is acknowledged. The traversal is on the ground(s) that the inventions of Groups I-IV have a unique technical feature which is not shown by the other groups. This is not found persuasive because *the unique technical feature shared by the groups, the depsipeptide of the formula of claim 1 is not a contribution over the art because it is anticipated by Kalbe et al. (2001, WO 01/62268 A1; and 2002, WO 02/00202A1), in the depsipeptide disclosed in formula Ia, page 13 and formula Ia, page 14, respectively, thus showing the peptides claimed as not being a contribution over the art.*

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Objections***

Claims 7-10, 13-15, and 17-19, are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. Namely, intrinsic properties or intended use do not further limit a product, where no further structural limitations are added.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant claims 15 and 17-19, the specific FKI-1033 compound is deemed to be isolatable from the genus, *Verticillium* (see specification pages 12-23). However, the only genus species for which this compound was found to be isolated from was that of *Verticillium sp.* FKI-1033 FERM BP-8219, e.g. claim 16.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565,

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1572, 41 USPQ2d 1661, 1966 (Fed. Cir. 1997); *In re Costello*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eft Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA, 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eft Lilly & CO.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP§ 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus, *if the genus has a substantial variance the disclosure must describe a sufficient variety of species to reflect the variation within that genus*. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, *the courts*

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*determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus.* In re Gostelli, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that 'distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. In the instant case, the five factors above have not been satisfactorily shown, namely as to what specific structure within this genus *Verticillium* must be present among the species, in order to isolate FKI-1033. were found to be satisfied by the description, not even a single species was found to be disclosed. Peptides being distinct compounds, like the agents from which they are isolated, Applicant was not in possession of any other *Verticillium sp.* other than *Verticillium sp.* FKI-1033 FERM BP-8219 for which isolation of FKI-1033 was clearly shown.

### ***Conclusion***

Claims 1, 2, and 16 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 5/9/2008

/Maury Audet/  
Examiner, Art Unit 1654

/Andrew D Kosar/  
Primary Examiner, Art Unit 1654